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In the Supreme Court of the United States

OCTOBER TERM, 1975

NATIONAL NUTRITIONAL FOODS ASSOCIATION AND SOLGAR COMPANY, INC., PETITIONERS

v.

CASPAR W. WEINBERGER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A-1 to A-32) is reported at 512 F.2d 688.[1] The opinions of the district court (Pet. App. B-1 to B-12, C-1 to C-15) are reported at 366 F.Supp. 1341 and 376 F.Supp. 142.

[1] An earlier decision of the court of appeals affirming the district court's denial of a preliminary injunction is reported at 491 F.2d 845 (C.A. 2).

JURISDICTION

The judgment of the court of appeals was entered on February 3, 1975. The petition for a writ of certiorari was filed on May 2, 1975. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the Food and Drug Administration (FDA) may, under Section 701(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), promulgate a regulation classifying oral preparations containing Vitamin A in excess of 10,000 IU (international units) per dosage unit or recommended daily intake, or Vitamin D in excess of 400 IU per dosage unit or recommended daily intake, as "drugs" under Section 201(g) of the Act, 21 U.S.C. 321(g).

2. Whether the "arbitrary, capricious" standard prescribed by 5 U.S.C. 706(2)(A), rather than the "substantial evidence" standard prescribed by 5 U.S.C. 706(2)(E), governs judicial review of regulations adopted in "notice and comment" rule making under 5 U.S.C. 553(c).

3. Whether high dosage forms of a drug that is used by many persons in quantities that have "a potentiality for harmful effect" may be classified as a prescription drug even though such a drug, if labeled with cautionary instructions, might be used safely by persons who follow the cautionary labeling.

STATUTES AND REGULATIONS INVOLVED

The relevant provisions of Sections 201, 502, 503, and 701 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 *et seq.*, as amended, 21 U.S.C. 321, 352, 353, and 371, are set forth in Pet. App. D. The relevant regulations, 21 C.F.R. 3.94 and 21 C.F.R. 3.95, are set forth in Pet. App. E.

STATEMENT

On December 14, 1972, the Commissioner of Food and Drugs commenced a rule-making proceeding by publishing a statement in the Federal Register, 37 Fed. Reg. 26618, giving notice of proposed regulations classifying oral preparations of Vitamins A and D in dosage units or recommended daily quantities in excess of 10,000 IU and 400 IU, respectively, as "drugs" and restricting the sale of such drugs to prescription dispensation pursuant to Section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. 353(b)(1). More than 2,500 written comments (including comments by petitioners) were submitted in response to that notice (Pet. App. A–5). The Commissioner published a report in the Federal Register on August 2, 1973, discussing the comments received and ordering that the regulations become effective on October 1, 1973. See 38 Fed Reg. 20723.

Petitioners, National Nutritional Foods Association and Solgar Co., Inc., brought suit in the United States District Court for the Southern District of New York on August 6, 1973, seeking declaratory and injunctive

relief to prevent enforcement of the regulations.[2] In April 1974 the district court granted the government's motion for summary judgment and dismissed the complaint (Pet. App. C).

On appeal the United States Court of Appeals for the Second Circuit held that the Commissioner has power to promulgate regulations having the binding force of law under Section 701(a) of the act, 21 U.S.C. 371(a) (Pet. App. A–10 to A–17), and that the Commissioner may utilize the notice-and-comment procedures prescribed by Section 4 of the Administrative Procedure Act, 5 U.S.C. 553(c), in adopting such regulations (*id.* at A–19 to A–21). The court of appeals also rejected petitioners' contention that Section 503(b)(1) of the Act, 21 U.S.C. 353(b)(1) (the "prescription" drug statute) precludes the use of notice-and-comment rule-making procedures for purposes of determining that particular drugs must be sold only on prescription (*id.* at A–17 to A–19). The court ruled that since the "substantial evidence" review standard of 5 U.S.C. 706(2)(E) is restricted to agency action in regard to which an evidentiary hearing is required, the "arbitrary, capricious" standard specified by 5 U.S.C. 706(2)(A) is applicable for purposes of determining the validity of the regulations (*id.* at A–21).

The court of appeals concluded, however, that a "serious question" exists regarding whether the Commissioner had classified properly the higher dosage

[2] Petitioners' request for a preliminary injunction was denied by the district court (366 F. Supp. 1341), and the denial was affirmed by the court of appeals (491 F. 2d 845).

level forms of Vitamins "A" and "D" as "drugs" under Section 201(g), rather than "foods," and remanded the case to the district court for the purpose of conducting a hearing to determine whether that particular determination was rational (*id.* at A–23 to A–24).[3]

ARGUMENT

1. Petitioners' primary contention is that the Commissioner of Food and Drugs had no power to promulgate regulations having binding effect under Section 701(a) of the Act, 21 U.S.C. 371(a).

Section 701(a) provides that "[t]he authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary."[4] Petitioners argue (Pet. 6–7) that the Commissioner is confined to the issuance of "interpretative" regulations, that is, regulations embodying non-binding statements of agency policy, under Section 701(a), and that any "substantive regulations" must be issued under Section 701(e) of the Act.

[3] The regulation involved in this case was also challenged in proceedings in the Northern District of Illinois. *National Health Federation* v. *Weinberger*, No. 73–C–2466. The district court dismissed the complaint, and the Seventh Circuit, referring to the present case, affirmed, on the ground that equity jurisdiction should not be invoked where the same issues were pending in litigation in another court. *National Health Federation* v. *Weinberger* (No. 74–1524, decided June 4, 1975).

[4] This authority has been delegated by the Secretary to the Commissioner of Food and Drugs. 21 C.F.R. 2.120(a)(1). See *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612, n. 2.

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Section 701(e) prescribes "* * * an elaborate procedure that must be followed by the FDA in promulgating regulations with respect to certain specifically enumerated subjects * * *" (Pet. App. A–11). Since the classification of a product as a prescription drug is not one of the enumerated categories of Section 701(e), the thrust of petitioners' argument is that the Commissioner cannot proceed by rulemaking, but must deal with the classification of prescription drugs in case-by-case adjudications.[5]

Contrary to petitioners' contention (Pet. 6), their challenge to FDA's rule-making authority under Section 701(a) is not "presented to this Court for the first time" in this case. As the court of appeals recognized, this Court's decisions in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, and its companion cases, *Ciba Corp.* v. *Weinberger*, 412 U.S. 640, *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, and *USV Pharmaceutical Corp.* v. *Weinberger*, 412 U.S. 655, interpreted Section 701(a) of the Act to authorize the issuance of binding regulations.

[5] As support for this argument petitioners erroneously assert that in the "prescription drug" statute, 21 U.S.C. 353(b)(1), Congress intended to preclude FDA from issuing binding regulations defining prescription drugs. This contention was correctly rejected by the court of appeals (Pet. App. A–17 to A–18), on whose opinion in this regard we rely. As the court noted, the Senate Report (S. Rep. No. 946, 82d Cong., 1st Sess. 4–5 (1951)), which discussed the version of the bill finally enacted, clearly indicates that FDA was to have the authority "to interpret and enforce" the definition of prescription drugs by the promulgation of regulations under Section 701(a) (Pet. App. A–18 to A–19, n. 10).

Thus, in *Weinberger* v. *Bentex Pharmaceuticals, Inc., supra,* this Court held that the Commissioner has power to determine the "new drug" status of particular drugs in administrative proceedings and rejected the contention that such determination must be made on a case-by-case basis in judicial proceedings to enjoin distribution of a product that FDA alleges to be a new drug. This Court said: "We think that it is implicit in the regulatory scheme, not spelled out *in haec verba,* that FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided, the 'new drug' status of individual drugs or classes of drugs. The deluge of litigation that would follow if 'me-too' drugs and OTC drugs had to receive *de novo* hearings in the courts would inure to the interests of manufacturers and merchants in drugs, but not to the interests of the public that Congress was anxious to protect * * * ." 412 U.S. at 653.

Petitioners' contention that prescription status of products must be determined in adjudicatory proceedings is essentially identical to the argument rejected in *Bentex Pharmaceuticals, Inc., supra.* The same considerations that underlie that decision are equally applicable here.[6]

[6] The court of appeals noted (Pet. App. A–13) that the interpretative-substantive dichotomy that petitioner urges is not a useful analytical concept. The correctness of that observation is demonstrated by petitioners' attempt to distinguish *Weinberger* v. *Hynson, Westcott & Dunning, Inc., supra,* as involving only an "interpretation" or "agency policy" (Pet. 11). The regulations upheld in *Hynson,* which, like the regulations involved here, were promulgated pursuant to Section 701(a), "'provide the basis for

2. The court of appeals, application of the 'arbitrary, capricious" standard in determining the validity of the regulations does not conflict with this Court's decision in *Abbott Laboratories* v. *Gardner,* 387 U.S. 136, as petitioners suggest (Pet. 11). *Abbott Laboratories* held that certain FDA regulations may be challenged in preënforcement declaratory judgment suits as well as in enforcement proceedings. The *Abbott Laboratories* opinion does not discuss the standard of review to be applied in determining the validity of a Section 701(a) regulation in either a preënforcement suit or an enforcement action, and does not imply that any standard other than the "arbitrary, capricious" standard is to be employed.

Petitioners incorrectly assert that this Court is now confronted "for the first time" with resolving the question of "the appropriate scope of review for all substantive agency action" (Pet. 19). This Court has held that the application of the "substantial evidence" standard of 5 U.S.C. 706(2)(E) is restricted to those cases "subject to the hearing provisions of 5 U.S.C. §§ 556 and 557 or 'otherwise reviewed on the record of an agency hearing provided by statute . . .' 5 U.S.C. § 706(2)(E)." *Weinberger* v. *Hynson, Westcott & Dunning, Inc., supra,* 412 U.S. at 622, n. 19. Since no evidentiary hearing is required in rule-making proceedings under Section 701(a) of the Act,[7] the

the determination whether there is 'substantial evidence' to support the claims of effectiveness for 'new drugs' * * *" (412 U.S. at 618), and, however petitioner would describe them, they have binding effect.

court of appeals correctly held that the "arbitrary, capricious" standard of 5 U.S.C. 706(2)(A) is the applicable standard of review for this regulation.

3. Under the "prescription drug" statute, 21 U.S.C. 353(b)(1)(B), a drug can be classified as a prescription drug if "because of its toxicity or other potentiality for harmful effect, or the method of its use" it "is not safe for use except under the supervision of a practitioner licensed * * * to administer such drug." The court of appeals correctly rejected the petitioners' contention (Pet. 19–21) that a drug can never be classified as a prescription drug if it can be safely used by persons who follow the cautionary labelling. The court of appeals properly concluded that it "was reasonable for the Commissioner to recognize that the risks of toxicity are increased by over-the-counter availability of readily ingestible, high dosage forms" (Pet. App. A–28) and noted that FDA "was not confronted with a case in which there was the mere possibility that a drug would be occasionally misused, but one in which the actual way in which the product is apparently used on a normal basis by many persons presents serious risks of toxicity" (Pet. App. A–29).

[7] The Administrative Procedure Act does require that an agency afford notice and an opportunity for interested persons to participate in rule-making proceedings "through submission of written data, views, or arguments *with or without opportunity for oral presentation*" (emphasis added). 5 U.S.C. 553(c). These requirements were satisfied here (see Pet. App. A–3 to A–6, A–19 to A–21). See also the court of appeals' opinion affirming the district court's denial of a preliminary injunction in this case, 491 F. 2d 845, 846 (C.A. 2).

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CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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